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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,236	12/08/2003	Robert Sixto JR.	ISD-056 C1	2523
36822 7590 06/05/2009 GORDON & JACOBSON, P.C. 60 LONG RIDGE ROAD SUITE 407 STAMFORD, CT 06902				
EXAMINER				
BLATT, ERIC D				
ART UNIT		PAPER NUMBER		
3734				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/730,236

Applicant(s)

SIXTO ET AL.

Examiner

Eric Blatt

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: the first page of the specification states, "This application is a continuation of U.S. Serial No. 09/981,775, filed June 25,2001." The present application claims priority to U.S. Serial No. 09/891,775.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

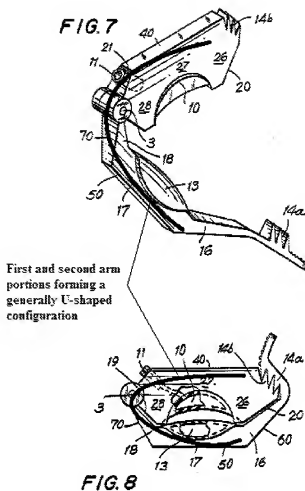
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Golyakhovsky et al. (US 4,800,879) in view of Yi (US 5,409,499).

Regarding claims 1, 2, 4-13, 15, 16 and 21, Golyakhovsky discloses a clip comprising first and second arms 2, 1 respectively, and a bridge portion 3 that joins the first and second arms. There is a retainer 7 extending from second arm 1 comprising hook portions 14a. First arm comprises catch portions 14b. The clip has a configuration wherein the arms extend substantially parallel to one another and the retainer 7 extends longitudinally from the second arm 1, and another configuration

wherein the retainer 7 is wrapped around the tip of the first arm 2 such that hook portions 14a engage the catch portions 14b. The clip, including the arms and the bridge portion comprise a substantially stiff plastic, and therefore, are substantially stiff. Examiner notes that bridge portion 3 defines a hinged joint, but holds that the joint may be considered substantially stiff since it comprises a substantially stiff material and has limited ability to elastically deform. Furthermore, bridge portion 3 allows movement along only one rotational dimension, and is substantially stiff in all other dimensions. The tip of the first arm is capable of piercing tissue. Retainer 7 has a length substantially 0.7 to 2 times the dimension between an outside of the first arm and an outside of the second arm. (Figure 8) The first and second arms and the bridge portion maintain a generally U-shaped configuration before during and after application of the clip to tissue of the patient. Figures 7 and 8 of Golyakhovsky are reproduced below with annotations illustrating the generally U-shaped configuration.



Thus, Golyakhovsky discloses all elements of claims 1, 2, 4-13, 15, 16 and 21 except for the arms and bridge portion comprising a single continuous piece of material. Yi teaches a related clip (Figure 1) having arms that undergo a rotation during application similar to that of the Golyakhovsky clip, and teaches that the bridge portion may be formed as a living hinge 12 such that the arms and bridge portion comprise a single continuous piece of material. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Golyakhovsky by

providing the bridge portion as a living hinge since this was a known alternative and the modification would not have produced unexpected results.

Regarding claims 3 and 14, Golyakhovsky does not disclose that the clip is made from a unitary piece of titanium or titanium alloy. Yi discloses that medical clips may be formed from titanium or titanium alloys. (Col. 3, Lines 50-60) It would have been obvious to one of ordinary skill in the art to make the clip of Golyakhovsky from titanium since it Yi teaches that titanium was known to be used for clip formation and its used would not have produced unexpected results.

Regarding claims 17-20, hook elements 14a are interpreted to define a plurality of retainers. Regarding claim 20, the claim does not require retainer portions that extend from the first arm. Since the retainer portions that extend from the second arm extend longitudinally beyond the first arm, the clip of Golyakhovsky meets the recited limitations of claim 20.

Regarding claim 22, Golyakhovsky does not disclose compressing the tissue prior to providing the first and second arms about the tissue. It would have been obvious to compress the tissue so that the arms may more easily fit over the tissue, and the tissue compression may be more carefully controlled.

Regarding claim 23, Golyakhovsky does not disclose a clip applier device. Golyakhovsky discloses that the clip may be easily applied over tissue within the body such as a blood vessel. It would have been obvious to provide a clip applier in order to reach remote anatomies while causing minimal tissue damage. Additionally, it would

have been obvious for the clip applier to provide the aforementioned compression since it may be difficult for a surgeon to reach the anatomy by hand.

Regarding claim 24, Golyakhovsky does not explicitly discuss piercing the retainer through tissue. During surgery, a target vessel may be embedded or muscle or connective tissue. Although the vessel may be removed from such tissue prior to clipping the vessel, some such tissue may remain. In order to clip the vessel, it would have been obvious to push the retainer around the vessel and through any surrounding tissue. This step would comprise piercing the retainer through tissue.

Regarding claim 25, Golyakhovsky discloses applying the clip on blood vessels. It would have been obvious to apply the clip on other, non-tubular tissues since clipping non-tubular tissues was well known in the art at the clip of Golyakhovsky would be capable of performing this function.

Regarding claim 26, Golyakhovsky discloses plastically deformably bending the retainer around the first arm. (Figure 8) Golyakhovsky does not specify what through what angle this bend occurs. It appears from Figure 8 that the retainer is bent through an angle of approximately 135 degrees while the most distal tip of the retainer bends back out and away from the first arm 2. It would have been obvious to one of ordinary skill in the art to bend this distal tip toward the first arm 2 such that it runs along the top surface of the first arm so that this tip does not extend away from the clip and risk damaging nearby tissues. So modified, the retainer would be bent through an angle of substantially 180 degrees.

Response to Arguments

Applicant's arguments filed 11 February 2009 have been fully considered but they are not persuasive.

Applicant argues that the arms of the Golyakhovsky clip do not maintain a generally U-shaped configuration before, during, and after application of the clip to tissue of a patient. As discussed in the body of the rejection, the clip arms and bridge portion are in a U-shaped configuration before application of the clip, and remain in a U-shaped configuration during and after application of the clip. (Figures 7 and 8) The arms and bridge portion thus maintain a U-shaped configuration before, during, and after application of the clip to patient tissue.

Applicant additionally argues that the tip of the retainer on the Golyakhovsky clip does not comprise a tissue piercing tip. Examiner maintains that said tip is capable of piercing through at least some types of patient tissue.

Applicant's arguments with respect to the recitation that the clip comprises a single continuous piece of material are moot in view of the new grounds of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric Blatt/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734